THE JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE
JOHNS HOPKINS BAYVIEW MEDICAL CENTER

May 23, 2007

Maryland Health Care Commission
Attn: Dr. David A. Neumann, PhD
Health Policy Analyst
4160 Patterson Avenue
Baltimore, Maryland 21215

Dear Dr. Neumann,

I have reviewed the draft regulations entitled "Research Waiver Applications for Participation in the Atlantic Cardiovascular Patient Outcomes Research Team Study of Non-Primary Percutaneous Coronary Interventions Performed in Maryland Hospitals without On-Site Cardiac Surgery."

I would like to comment on three specific aspects of this draft.

First, in section .02 entitled "Purpose," section C, the regulations propose limiting the number of hospitals that may be granted permission to participate in the C-PORT E study by the Maryland Health Care Commission (MHCC) to six hospitals.

Per the MHCC Executive Director's Recommendation to the MHCC Commissioners dated April 13, 2007 (page 9), the C-PORT E study currently has 27 hospitals enrolled in states other than Maryland. Based on current projections, expansion to 40 hospitals would enable the study to be completed in November 2008. Therefore, the C-PORT E study would benefit, in terms of achieving full enrollment, from at least 13 more hospital participants. Limiting the number of Maryland hospitals to six will hinder overall study enrollment and delay completion of this study. Consequently, the answer to the public policy question addressed by this study – is non-primary angioplasty safe and effective at hospitals without on-site cardiac surgery? – will also be delayed.

Additionally, limiting the number of Maryland hospitals participating in this study will impede patient access to health care. At present, patients who receive diagnostic catheterization at hospitals without on-site cardiac surgery are placed in a difficult situation if they are diagnosed with coronary artery disease. Two common scenarios occur:

1) The patient is transferred with an arterial sheath in place to a hospital with on-site surgery, and the subsequent delay increases the patient's risk of vascular complications; or
2) The patient is forced to wait at least 24 hours in the hospital (or longer if an outpatient) to receive the angioplasty procedure at another hospital, prolonging the patient's length of stay and requiring re-admission at another hospital.

Both scenarios invariably increase the cost of health care to the patient, as well as to all Marylanders who share in this cost. By allowing more hospitals to participate in this study, the Commission will 1) facilitate its enrollment and completion and 2) improve access to and decrease the cost of providing this service to Marylanders.

Second, in section 0.04 "Review of Applications", section A, subsection (c), the regulations propose that applicants must "meet and maintain a minimum volume of 200 PCI's annually"and failing to perform this mimimum requirement is considered grounds for waiver revocation, beginning in year 1 (section 0.06, section A, subsection (4)).

In assessing the current status of the C-PORT elective study, the Executive Director (in abovementioned April 13, 2007 memorandum) informed the Commission that the annualized enrollment of the current participating 27 hospitals was 127 patients per year, noting that none of the sites were active for more than 9 months. He therefore notes, "Study accrual, although not matching the rate assumed in the protocol, appears satisfactory."

Thus, the group of current non-Maryland participants in C-PORT E, as noted by your executive director, do not meet the proposed standard of 200 PCI's annually; consequently, most, if not all, of these hospitals would fulfill a salient criteria for waiver revocation in the first year. It is reasonable to expect that participating hospitals in Maryland would have similar patient enrollment rates and PCI volumes as those of current C-PORT E participants. Therefore, it would be far more realistic and fair to introduce either 1) a graded increase in the minimum number of PCI's required to support a waiver and/or 2) a longer time period (i.e. 2 - 3 years) over which these hospitals would be required to meet this mimimum requirement of 200 PCI's annually.

Finally, in section .03 "Waiver Application," section (B), the draft regulations propose more stringent eligibility requirements for participation for hospitals in the Greater Baltimore/Washington areas in comparison with hospitals on the Eastern Shore or Western Maryland. Specifically, the proposal states that individual Greater Balitmore/Washington hospitals are eligible to apply for C-PORT E if, at time of application, the hospital has a 2-year waiver to perform PCI. On the other hand, if the hospital is from the Eastern Shore or Western Maryland, this hospital only has to demonstrate that they have permission to perform PCI, have been doing it for six months, and have a minimum of 18 primary PCI procedures.

This proposed regulation is highly discriminatory in favor of Eastern Shore/Western Maryland hospitals. Currently, no hospital in the Greater Baltimore or Washington area has a 2-year waiver to perform primary PCI; therefore, no hospital in the Greater Baltimore or Washington area would be currently eligible to apply for participation in the C-PORT E study. This would occur despite many of these same hospitals having at least four years of experience, with significant improvements in state-mandated outcomes, as participants in the original C-PORT study and registry.

On the other hand, Eastern Shore/Western Maryland hospitals have, at best, less than a year's experience in performing primary PCI without on-site surgery. In addition, these hospitals have no track record in terms of safety or efficacy in performing primary PCI. Therefore, this regulation virtually ensures that Maryland hospitals with the least experience performing primary PCI without on-site surgery will be the only hospitals eligible to apply for non-primary PCI. Clearly, this is contrary to the aims of the study and answering the public policy question at hand.

Thank you for your careful consideration of these concerns as you develop regulations for conducting the C-PORT E study in Maryland.

Sincerely,

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